

REMARK

Claims 1-34 have been canceled without prejudice or disclaimer. Applicants reserve the right to file one or more continuation or divisional applications directed to the canceled subject matter. New claims 35-37 have been added. New claims 35-37 have been added. New claims 35-37 finds basis in the specification paragraph 31, 39, 62-63, Table 1, Table 2a, Table 4, paragraph 79, Table 6, and paragraph 86 for example. Paragraphs [0009] and [0010] have been amended to recite the Journal title, volume, issue number, and page number of the cite as required by the Office. No new matter has been added. Entry of said amendment and reconsideration is respectfully requested.

Information Disclosure Statement

It is unclear what the Office wants Applicants to do with respect to the information disclosure statement. Clarification is requested. Applicants have submitted any references they were aware of that is material to the patentability of any existing claim. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98.

SPECIFICATION

The objection to the specification because recitations are incomplete for not reciting author, source, date of publication, volume, issue number and pages is traversed. Applicants by way of the above amendment have corrected paragraphs [0009] and [0010] as required by the Office. Withdrawal of the instant objection is respectfully requested.

The rejection of claims 1,2,6, and 8, as it now pertains to new claims 35 and 37, under 35 USC 112, first paragraph.

The Office states that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants submit that new claims 35 and 37 are drawn to deposit NRRL B-30514 which has been deposited under the Budapest Treaty with a recognized public Budapest Treaty

respository, at the USDA Agricultural Research Service Patent Culture Collection, National Center for Agricultural Utilization Research, 1815 N. University Street, Peoria, Illinois 61604. The deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application.

The Office requires Applicants to amend the specification to recite the date of the deposit and the complete name and full street address of the depository. This is unclear to Applicants since paragraph [0031] contains this information. Clarification is requested.

The rejection of claims 1,2,6, and 8, as it now pertains to new claim 38, under 35 USC 112, first paragraph because the specification, while being enabling for an isolated bacteriocin produced by a lactic acid producing bacterial strain having the identifying characteristics of a strain selected from the group consisting of NRRL B-30514, having SEQ ID NO 1, does not reasonably provide enablement for a bacteriocin having an amino acid sequence of SEQ ID NO 1.

The Office states that the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to make and use the invention commensurate in scope of these claims.

New claim 38 does not contain the language "...having an amino acid sequence of SEQ ID NO 1. Withdrawal of the instant rejection is respectfully requested.

The rejection of claims 1,2,6, and 8, as it now pertains to new claims 35-37, under 35 USC 102(b) as being anticipated by Kanatani, K. et al (Isolation and characterization of Acidocin A and cloning of the bacteriocin gene from *Lactobacillus acidophilus*, Applied and Environmental Microbiology, 1995, 61(3): 1061-1067) is respectfully traversed.

The Office states that Kanatani et al disclose bacteriocin produced by *Lactobacillus acidophilus* which is active against closely related lactic acid bacteria citing page 1601 as evidence. The Office then states that the microorganisms disclosed in the instant specification are characterized by their anti-bacterial properties citing page 6, paragraph 007 as evidence and that the microorganisms disclosed in the prior art is known to display antimicrobial activity citing page 1061 as evidence. The Office further states that Kanatani et al disclose in Figure 3 the

deduced amino acid sequence which is identical to an amino acid sequence of the instantly claimed SEQ ID NO 1 citing paging 1064. The Office concludes that the bacteriocin produced by *Lactobacillus acidophilus* would have the identifying characteristics of the claimed bacterial strain.

Applicants respectfully submit that Kanatani et al. fails to anticipate the instantly claimed invention. The amino acid sequence on page 1064 of Kanatani is not the same amino acid sequence of SEQ ID NO 1. The reference is silent as to an isolated *Lactobacillus salivarius* having the identifying characteristics of NRRL B-30514. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference discloses all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown. (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974))

The rejection is improper. Applicants respectfully request withdrawal of the instant rejection.

The rejection of claims 1,2,6, and 8, as it now pertains to new claims 35-37, under 35 USC 102(b) as being anticipated by Robredo, B. et al, Bacteriocin production by *Lactobacillus salivarius* of animal origin, *Journal of Clinical Microbiology*, 2000, 38 (10): 3908-09) is respectfully traversed.

The Office states that Robredo et al. disclose that bacteriocins are secreted oligopeptides, proteins or protein complexes with antimicrobial activity against strains taxonomically related to the producer organism. The Office further states that Robredo et al. disclose the production of bacteriocins isolated from *Lactobacillus salivarius* and cites page 3908. The Office concludes that inherently the bacteriocin of the prior art produced by *Lactobacillus salivarius* would have an amino acid sequence of SEQ ID NO 1 and the identifying characteristics of the claimed strain.

Applicants submit that Robredo fails to anticipate the presently claimed invention. Note on page 3908, right column, first full paragraph, the reference states that bacteriocin activity was detected in 11 out of 18 *L. salivarius* isolates and NONE of these showed growth inhibition activity against *Enterococcus*, *Bacillus* or *E. coli*. Applicants direct attention to Tables 4 and 6 of the present invention showing that Bacteriocin OR-7 has growth inhibitory activity against *E. coli*. Furthermore, the reference fails to anticipate the claims to an isolated *Lactobacillus salivarius* NRRL B-30514, since the reference fails to teach a bacteriocin having the same activity as the instantly claimed invention. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference disclose all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974)).

The rejection is improper. Applicants respectfully request withdrawal of the instant rejection.

The rejection of claims of claims 1,6, and 8, as it now pertains to new claims 35-37, as being anticipated by Ocana, V. et al. (Characterization of bacteriocin-like substance produced by a vaginal *Lactobacillus salivarius* strain, Applied and Environmental Microbiology, 1999, 65(12): 5631-5635) is respectfully traversed.

The Office states that Ocana et al disclose bacteriocins synthesized by bacteria having a narrow spectrum of activity, having the ability to inhibit a wide range of gram-positive bacteria citing page 5631. The Office further states that Ocana et al disclose that *L. salivarius* was selected because of its ability to inhibit growth of microorganisms. The Office concludes that inherently, the bacteriocin of the prior art produced by *Lactobacillus salivarius* would have the identifying characteristics of the claimed bacterial strain.

Applicants submit that the bacteriocin synthesized by the *L. salivarius* of Ocana et al, does not anticipate the instantly claimed invention. Note Table 1 of the reference where *E. coli* and *Klebsiella* were resistant to the disclosed bacteriocin. Note Table 4, for example, of above-referenced specification which shows that the instantly claimed bacteriocin inhibits growth of *E. coli* and *Klebsiella*. Furthermore, the reference fails to anticipate the claims to an isolated *Lactobacillus salivarius* NRRL B-30514, since the reference fails to teach a bacteriocin having the same activity as the instantly claimed invention. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech*

Inc., 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference disclose all the claimed elements in isolation. With respect to NRRL B-3051, note that In re Mancy states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (In re Mancy, 182 USPQ, 303, (CCPA, 1974)

The rejection is improper. Applicants respectfully request withdrawal of the instant rejection.

The rejection of claims 1,2,6, and 8, as it now pertains to new claims 35-37, under 35 USC 102(e) as being anticipated by Collins et al (U.S. Patent Application 2004?0214304A) is respectfully traversed.

The Office states that Collins et al disclose probiotic strains from *Lactobacillus salivarius* and disclose the use of gram positive, catalase negative rod-shaped bacteria isolates and cite page 4, 0068. The Office further states that Collins et al disclose a segment of amino acids that is identical to that of instantly claimed SEQ ID NO 1 of the present invention. By all comparative data the strain of the prior art and the instantly claimed strain, absent evidence to the contrary, are the same. The Office concludes that the strain of the prior art inherently anticipates the instantly claimed strain because applicants' definition in the instant application, the *Lactobacillus salivarius* PVD 32 strain is gram positive, catalase negative and pleomorphic rods. The Office additionally concludes that the strain of the prior art would inherently have identifying characteristics of the claimed strain.

Applicants respectfully submit that the Collins et al. reference fails to anticipate the

presently claimed invention. The Office states that Collins et al disclose a segment of amino acids that is identical to that of instantly claimed SEQ ID NO 1. However, upon comparison of SEQ ID NO 1 and that disclosed in published application, Applicant found no similarity. Furthermore, the bacteriocin of SEQ ID NO 1 is active against *E. coli*, *S. typhimurium*, *S. enteritidis*, and *Campylobacter*, the bacteriocins of Collins et al. fail to inhibit these microorganisms. The Federal Circuit states that the anticipation determination is viewed from one of ordinary skill in the art and that there must be no difference between the claimed invention and the reference disclosure as viewed by a person of ordinary skill in the field of the invention, *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F. 2d 1565, 18 USPQ2d 1001, 1010, (Fed. Cir. 1991). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. It is not enough, however, that the reference disclose all the claimed elements in isolation. With respect to NRRL B-3051, note that *In re Mancy* states if a strain was unknown to those of ordinary skill in this art area, one cannot choose from the unknown (*In re Mancy*, 182 USPQ, 303, (CCPA, 1974))

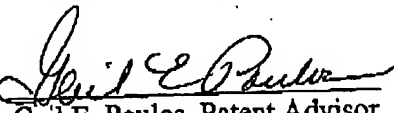
The rejection is improper. Applicants respectfully request withdrawal of the instant rejection.

It is believed that all of the claims are in condition for allowance. Accordingly, it is respectfully requested that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

In the event this paper is deemed not timely filed, the undersigned hereby petitions for an appropriate extension of time. The fee for such extension may be charged to Deposit Account 50-2134, along with any additional fees which may be required with respect to this paper.

Respectfully Submitted,


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DATE


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CERTIFICATE OF FILING VIA FACSIMILE

The undersigned hereby certifies that the attached AMENDMENT¹, was this day, SEPTEMBER 6, 2005, filed in the United States Patent and Trademark Office via facsimile to facsimile number 571-273-8300 Total Pages: 15


Gail E. Poulos